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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,348	03/24/2005	Ilan Shalev	331/04204	5391

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WOLF, BLOCK, SCHORR & SOLIS-COHEN LLP  
250 PARK AVENUE  
NEW YORK, NY 10177

EXAMINER
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MEHTA, BHISMA

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/509,348

Applicant(s)

SHALEV, ILAN

Examiner

Bhisma Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 16-18, 25, 36-38, 40-43 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-24, 26-35, 39, and 44-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted claim 48 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 48 is a method claim. The pending claims 1-47 and new claim 48 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products as claimed can be used for a materially different process such as for delivering medication into a patient's body.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 48 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Objections***

2. Claims 10, 21-23, and 28 are objected to because of the following informalities: Claim 10 recites the limitation "said body tissue" in line 1. Claims 21-23 recite the limitation "said intake of fluid" in lines 2 and 3. Claim 28 recites the limitation "said fluid" in line 3. Claim 33 recites the limitation "said at least one expandable element" in lines

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1 and 2. Claim 34 recites the limitation "said at least one expandable element" in lines 2 and 3. Claim 35 recites the limitation "said at least one expandable element" in lines 2 and 3. There is insufficient antecedent basis for these limitations in these claims. It is suggest that for claims 10, 21-23, and 28, the word "said" should be replaced with "the". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 9-15, 19, 21-24, 27-34, 39, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan et al (U.S. Patent No. 5,609,574). In Figures 1 and 1E, Kaplan et al show an apparatus or device comprising a hollow tube (20) with apertures (22 and 34), expandable resilient extensions (28 and 32), and an activating mechanism (40). The extension is operative in a deflated or first position and an inflated or second position by the manual activation of the activating mechanism. The activating mechanism includes a reservoir containing expansion fluid which is used to expand the extension. In the first position, the extension is near the aperture (22). In

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the second position, at least part of the extension extends away from the aperture.

Figure 6 shows the hollow tubes with additional apertures (34). As to claims 5-7, 9, and 10, in Figures 8A, 8B, and 17A – 17D, an impediment (S) in the form of an aggregate of solid material or inflamed body tissue which is located down flow from the hollow tube or at least partly within the hollow tube is shown. In lines 46-56 of column 13, Kaplan et al disclose that an agent or impediment may be located partly within the hollow tube. As to claims 11 and 12, Kaplan et al teach that the device may be left in a the patient's body between treatments (lines 1-10, column 17) and disclose the claimed structural elements of the device, thus, the device of Kaplan et al is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 21-24, Kaplan et al teach that the delivery of the fluid may be performed before, after, or during the inflation of the extension (lines 18-31, column 16). As to claim 27, the apertures in Figure 6 would be covered by the wall tissue of a patient's vein as the device is advanced in a deflated configuration through the narrow passages of the patient's body. As to claims 28-31, Kaplan et al disclose the tube comprising or having a material or fluid which is delivered into the particular portions of a patient's body which include fluids which are capable of preventing aggregation of solids, clot formation, body tissue inflammatory response, and bacteria colonization (see lines 53-67 of column 9 and lines 36-49 of column 11). As to claims 44 and 45, Kaplan et al teach that the device may be adapted for veins, arteries, and other locations in a patient's body and disclose the claimed structural elements of the device, thus, the device of Kaplan et al is capable of being adapted for an arm vein and fro an non-vein vessel. As to claims 46 and 47, at

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least a part of the extension is axially displaced when it is in the inflated position and at least a part of the extension is radially displaced when it is in the inflated position.

5. Claims 1, 3, 5-7, 9-15, 19-24, 26-35, 39, and 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Zadno-Azizi (U.S. Patent No. 6,958,059). In Figures 12 and 13, Zadno-Azizi shows an apparatus or device comprising a hollow tube (14, 420) with apertures (240, 460), a resilient expandable extension (12, 422), and an activating mechanism. The extension is operative in a deflated or first position and an inflated or second position by the automatic activation of the activating mechanism (see lines 9-32 of column 6). The activation can also be considered to be partly manual (rotation of the knob). The activating mechanism includes a reservoir containing expansion fluid which is used to expand the extension. In the first position, the extension is near an aperture. In the second position, at least part of the extension extends away from the aperture. As to claims 5-7, 9, and 10, in Figures 9A and 9B, an impediment (S) in the form of an aggregate of solid material or inflamed body tissue which is located down flow from the hollow tube or at least partly within the hollow tube is shown. As to claims 11 and 12, Zadno-Azizi discloses the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 21-24, Zadno-Azizi discloses the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being adapted such that delivery of the fluid may be performed before, after, or during the inflation of the extension. As to claim 26, in Figure 11B, Zadno-Azizi show an aperture (328) which is covered by the extension

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(318) in a first or deflated position. As to claim 27, the apertures in Figure 12 would be covered by the wall tissue of a patient's vein as the device is advanced in a deflated configuration through the narrow passages of the patient's body. As to claims 28-31, Zadno-Azizi discloses the tube comprising or having a material or fluid which is delivered into the particular portions of a patient's body which include fluids which are capable of preventing aggregation of solids, clot formation, body tissue inflammatory response, and bacteria colonization (see line 44 of column 13 to line 6 of column 14). As to claim 35, Zadno-Azizi teaches using an expansion fluid containing drugs which affect the formation of impediments (see lines 31-56 of column 13) and an expandable extension (422) which is permeable to the drugs (see line 44 of column 17 to line 22 of column 18). As to claims 44 and 45, Zadno-Azizi teaches that the device may be adapted for veins, arteries, and other locations in a patient's body and disclose the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being adapted for an arm vein and for a non-vein vessel. As to claims 46 and 47, at least a part of the extension is axially displaced when it is in the inflated position and at least a part of the extension is radially displaced when it is in the inflated position.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al in view of admitted prior art (admission). Kaplan et al disclose a device which is used in a patient's body and which is capable of dislodging an impediment. However, Kaplan et al are silent on the specifics of the impediment being a venous valve. Admission discloses numerous impediments or blockages which may be present in a patient's body including a vein valve, a regularly occurring part of the body's vein system, which may block an aperture of a inserted catheter or tube (see lines 5-13 of page 2 of applicant's specification). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of Kaplan et al to dislodge or unblock a venous valve as taught by Admission as a venous valve is a well known form of blockage that can occur in the patient's body.

### ***Response to Arguments***

8. Applicant's arguments filed November 27 2006 have been fully considered but they are not persuasive. Applicant's arguments that a prima facie rejection has not been established are not considered persuasive.

As to the rejection of claims 1-7, 9-15, 19, 21-24, 27-34, 39, and 44-47 under 35 U.S.C. 102(b) as being anticipated by Kaplan et al (U.S. Patent No. 5,609,574), the extensions of Kaplan et al are operative to be in the at least two positions as claimed relative to the aperture (22) and relative to the apertures (34). This is clearly seen in the figures and especially in Figure 6. In response to applicant's argument that Kaplan does not teach relative movement of the at least one extension with respect to the



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aperture, from the first position to the second position, resulting in the dislodgment of an impediment from the aperture and does not teach the apparatus being implanted in a vein for the purpose of intake of fluid, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

As to the rejection of claims 1, 3, 5-7, 9-15, 19-24, 26-35, 39, and 44-47 under 35 U.S.C. 102(e) as being anticipated by Zadno-Azizi (U.S. Patent No. 6,958,059), the extensions of Zadno-Azizi are operative to be in the at least two positions as claimed relative to the apertures (240, 460). This is clearly seen in the figures and especially in Figures 10A and 10B. In response to applicant's argument that Zadno-Azizi does not teach relative movement of the at least one extension with respect to the aperture, from the first position to the second position, resulting in the dislodgment of an impediment from the aperture and does not teach the apparatus being implanted in a vein for the purpose of intake of fluid, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It should be noted that in Figures 6C and 6D, aspiration or the intake of fluid is being performed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
BM

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

